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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,364	05/09/2005	Yoshinori Hishikawa	1029650-000170	4895

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EXAMINER
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MATNEY, BROOKE MARIE

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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04/28/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/534,364	<b>Applicant(s)</b> HISHIKAWA ET AL.	
	<b>Examiner</b> Brooke M. Matney	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "the other side" in line 4. There is insufficient antecedent basis for this limitation in the claim. This limitation is also unclear. For the purpose of examination, Examiner will interpret this limitation to mean the other end of said tube.

4. As to claim 9, it is unclear if the limitations a tube, a connection part, and a liquid container are meant to be distinct from the tube, connection part, and liquid container in claim 1, because they have the same name but are not written as "said tube, etc.". For the purposes of examination, Examiner will interpret them to be distinct from the parts of claim 1.

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5. Claim 10 has the limitation "a connector" in line 3 and "said connector" in line 5. These are not claimed in a way that makes them clearly distinct, but Examiner believes they are intended to be two distinct parts and will interpret them that way.

6. Claim 10 is unclear as to whether the connector or the "other end side of a tube" has the connection part. It is also unclear as to what the meaning of "other end side" in line 3 and "one end side" in lines 3-4 is. It is also unclear as to what the connector is connected to when reading the limitation "said connector of said liquid transfusing tube can be simultaneously connected" (lines 5-6). For the purposes of examination, Examiner will interpret claim 10 to mean that the liquid dosing part side connector is branched into a plurality of parts so that a connector connected to a second liquid container can be connected to a connector of said liquid transfusing tube.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gula et al. [USPN 4,447,230].

As to claim 1, Gula et al. discloses a liquid transfusing tube comprising:  
a tube (tube 78, Fig. 2) constituting a liquid transfusing channel and having an axis; a connector (26, Fig. 1) provided at one end part of said tube; and  
a connection part (connector connecting tube 78 to bag 74, Fig. 2) provided on

the other side of said tube and connected to the side of a containing part containing a transfusion; wherein said connector includes a male connector and a female connector (tee spike distal/proximal ends (26)), and the axis of said male connector and the axis of said female connector substantially coincide with each other (Fig. 1), and the axis of said tube is substantially orthogonal to the axis of the male connector and the axis of said female connector (Fig. 2, at point where tube 78 meets connector 26).

As to claim 5, Gula et al. discloses comprising: a liquid dosing part for dosing a patient with said transfusion (assembly from 12 to male luer lock adapter 22), said liquid dosing part having a liquid dosing part side connector (male luer lock adapter 22, or tee spike 26 that adapter 22 can be connected to) capable of being connected to one of said male connector and said female connector of said connector of said liquid transfusing tube (22 is connected to the connector of Gula et al. via female luer lock adapter 24 and intermediary tee spikes 26; 22 is also capable of being attached to any of the female connectors 28 on the tee spikes 26, and then 26 can be interpreted as the liquid dosing part side connector); wherein in the condition where one of said male connector and said female connector of said connector of said liquid transfusing tube and said liquid dosing part side connector of said liquid dosing part are connected with each other, the other of said male connector and said female connector of said connector of said liquid transfusing tube can be connected to another liquid transfusing tube other than said liquid transfusing tube (Fig. 2); and the other of

said male connector and said female connector of said connector of said liquid transfusing tube is exposed as an open connection port to receive a male or female connector of the another liquid transfusing tube (in the case where 22 is attached to a female connector 28, 24 would be open to receive another male luer lock adapter).

As to claims 6 and 7, Gula et al. discloses wherein said liquid dosing part has a bacteria-removing filter (32, Col. 3, ll. 55-65), wherein said bacteria-removing filter is provided on the downstream side relative to said liquid dosing part side connector (Fig. 1).

As to claim 8, Gula et al. discloses wherein said liquid dosing part has a mixing injection port (43) on the downstream side (defined as fluid flow from 12 to 58) of said bacteria-removing filter.

As to claim 9, Gula et al. discloses wherein the other end side of a tube (82, Fig. 2) having on its one end side a connection part (connector between tube 82 and bag 76) connected to a liquid container (76) is connected to said liquid dosing part side connector (via tee spike 26).

As to claim 10, Gula et al. discloses wherein said liquid dosing part side connector (tee spike 26 when attached to adapter 22) is branched into a plurality of parts so that a connector provided on the other end side of a tube having on its one end side a connection part connected to another liquid container other than said liquid container and said connector of said liquid transfusing tube can be

simultaneously connected. They can be connected via the male and female connecting parts of tee spikes 26 (Fig. 2).

As to claim 11, Gula et al. discloses wherein the connector is directly connected to said tube (Fig. 2).

As to claim 12, Gula et al. discloses wherein the male connector and the female connector are on opposing sides of said connector (see tee spike connectors 26, Fig. 1).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gula et al. [USPN 4,447,230] in view of Boyle et al. [USPN 4,734,091].

Gula et al. meets the claim limitations as described above except for the channel changeover function and inner cavity fluid communication.

However, Boyle et al. teaches a filtered manifold apparatus and method of ophthalmic irrigation.

As to claims 3-4, Boyle et al. teaches a liquid transfusing assembly (Fig. 1) with a liquid transfusing tube (60) connected to a plurality of 3-way stopcock valves (54) connected to a transfusion source (12) with each valve configured to

change fluid channels via the valve stem (110) to fluidly connect the male/female ends (Figure 3, Col. 4, ll. 10-45).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to incorporate the 3-way valve stems of Boyle et al. to the system of Gula et al. in order to allow for fluid control through the infusion tube assembly and allow for fluid channel closing when a valve is not in use. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Boyle et al. (Cols. 1-2).

### ***Response to Arguments***

11. Applicant's arguments filed 11/17/2009 have been fully considered but they are not persuasive.

Firstly, Applicant's Representative argues that Gula et al.'s "tube" is not substantially orthogonal to the axis of what the Official Action says are the male and female connectors. Secondly, Applicant's Representative argues that Gula et al.'s tee fitting 26 ("connector") is not provided at one end part of Gula et al.'s "tube" as recited in claim 1. As can be seen in the 102 rejection of claim 1 in this action, Examiner is now identifying tube 78, seen in Fig. 2, as the tube taught by Gula. Therefore, the male and female connectors are orthogonal to the axis of tube 78 where the tube meets the connectors, and the tee fitting 26 is provided at one end of the tube.



Thirdly, Applicant's Representative argues that the result of the combination of features results in an open port for connection of another liquid transfusing tube is always present and the liquid transfusing line can be extended quickly and assuredly. However, this feature is not positively claimed in a way that distinguishes it over the prior art of record.

Applicant's Representative also argues that claims 3-12 are patentable because they depend on an allowable base claim (1). However, since Examiner does not believe claim 1 to be allowable, Examiner does not find claims 3-12 to be allowable either.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brooke M. Matney whose telephone number is (571)270-1457. The examiner can normally be reached on Monday-Thursday 9AM-7PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brooke M Matney/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art  
Unit 3763